COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 01/IX/2006
C(2006)4066

NOT FOR PUBLICATION

COMMISSION DECISION

of 01/IX/2006

amending the marketing authorisation for "Apidra - Insulin glulisine", a medicinal product for human use, granted by Decision C(2004)3653

(ONLY THE GERMAN TEXT IS AUTHENTIC)

COMMISSION DECISION

of 01/IX/2006

amending the marketing authorisation for "Apidra - Insulin glulisine", a medicinal product for human use, granted by Decision C(2004)3653

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular the first subparagraph of Article 6(10) thereof,

Having regard to the application(s) submitted by Sanofi-Aventis Deutschland GmbH on 30 April 2006 under Article 6(1) of Commission Regulation (EC) No 1085/2003,

Having regard to the opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 27 July 2006,

Whereas:

(1) An examination of the major variation type II to the terms of the marketing authorisation for the medicinal product "Apidra - Insulin glulisine", which is entered in the Community Register of Medicinal Products under No(s) EU/1/04/285/001-028 and the placing on the market of which was authorised by Decision C(2004)3653 of 27 September 2004, has shown that the product remains in compliance with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3].

(2) It is therefore appropriate to accept the application(s) in respect of (a) major variation(s) to the terms of the marketing authorisation and to amend Decision C(2004)3653 accordingly.

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[1] OJ L 136, 30.4.2004, p. 1
[2] OJ L 159, 27.6.2003, p. 24.
[3] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p.34).

(3) For the sake of clarity and transparency, it is advisable, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C (2004)3653 should therefore be replaced,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2004)3653 is amended as follows:

1) The following numbers are added to Article 1 and entered in the Community register of medicinal products:

EU/1/04/285/029	Apidra-100 Units/ml-Solution for injection-Subcutaneous use-pre-filled pen (glass) (SoloStar)-3 ml-1 pre-filled pen
EU/1/04/285/030	Apidra-100 Units/ml-Solution for injection-Subcutaneous use-pre-filled pen (glass) (SoloStar)-3 ml-3 pre-filled pens
EU/1/04/285/031	Apidra-100 Units/ml-Solution for injection-Subcutaneous use-pre-filled pen (glass) (SoloStar)-3 ml-4 pre-filled pens
EU/1/04/285/032	Apidra-100 Units/ml-Solution for injection-Subcutaneous use-pre-filled pen (glass) (SoloStar)-3 ml-5 pre-filled pens
EU/1/04/285/033	Apidra-100 Units/ml-Solution for injection-Subcutaneous use-pre-filled pen (glass) (SoloStar)-3 ml-6 pre-filled pens
EU/1/04/285/034	Apidra-100 Units/ml-Solution for injection-Subcutaneous use-pre-filled pen (glass) (SoloStar)-3 ml-8 pre-filled pens
EU/1/04/285/035	Apidra-100 Units/ml-Solution for injection-Subcutaneous use-pre-filled pen (glass) (SoloStar)-3 ml-9 pre-filled pens
EU/1/04/285/036	Apidra-100 Units/ml-Solution for injection-Subcutaneous use-pre-filled pen (glass) (SoloStar)-3 ml-10 pre-filled pens

2) Annex I is replaced by the text set out in Annex I to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 2

This Decision is addressed to Sanofi-Aventis Deutschland GmbH, Brueningstrasse, 50 - D 65926 Frankfurt am Main, DEUTSCHLAND.

Done at Brussels, 01/IX/2006

For the Commission
Heinz ZOUREK
Director-General